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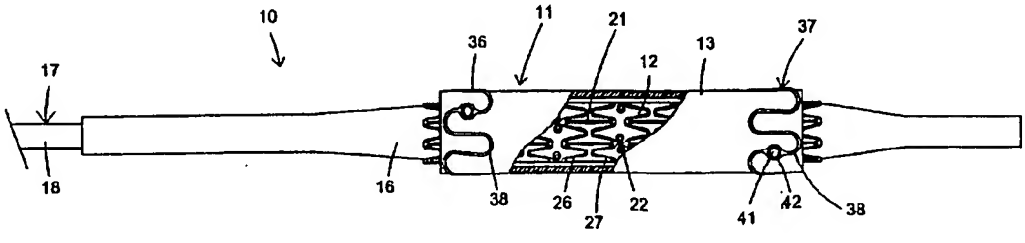
(54) Title: STENT GRAFT ASSEMBLY AND METHOD



(57) Abstract: The present invention generally concerns a stent graft for implantation in a vessel in a patient. The invention includes two aspects. The first aspect provides a stent graft formed of an expandable metal skeletal structure and having a graft in the form of a polymeric sleeve extending over the stent, and an expandable security ring securing each end of the graft to a corresponding end region of the stent. The second aspect provides inner and outer sleeves enclosing a plurality of separate expandable metallic rings and flexible bands.

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Stent Graft Assembly and Method

Field of the Invention

The present invention relates to a stent graft assembly and method and more particularly to a covered flexible stent graft which includes security rings.

Background of the Invention

Previous patent applications have composite expandable stents with polymeric coverings. See, for example, U.S. Patent No. 5,674,241. In connection with the expandable stent and the polymeric covering forming a graft carried thereby it has been found that it may be possible for the stent to move or become dislodged from its most desirable position on the stent. In addition, it has been found that such stent grafts have not had the desired flexibility while retaining a consistent circumferential support. There is therefore a need for a new and improved stent graft assembly and method which overcomes these possible difficulties.

Summary of the Invention

In one aspect, the invention includes a stent graft for implantation in a vessel of a patient. The stent graft includes a stent formed of an expandable metal skeletal structure with first and second end regions, a graft in the form of a polymeric sleeve extending over at least a portion of the stent, the graft having first and second ends, and an expandable security ring securing each end of the graft to a corresponding end region of the stent.

In one embodiment the security rings are formed of metal and have an roughened surface for engaging the outer surface of the graft to enhance frictional engagement between the security ring and the graft. In a related embodiment, the security rings are formed of stainless steel, titanium, or nitinol. In another related embodiment, the stent is formed of stainless steel, titanium, or nitinol. In a related embodiment, the security rings are formed of elongate metal elements having convolutions therein to permit expansion of the security ring.

In a related embodiment, the stent graft includes a radiopaque marker carried by the security ring. The security rings may include an eyelet which has radiopaque material disposed therein. The radiopaque marker is capable of projecting in a direction so that it forms a depression in the graft to help ensure that the graft and ring will not become displaced with respect to the stent. In another embodiment, a radiopaque marker is carried

by the stent. The stent can include an eyelet. The radiopaque material can be disposed in the eyelet. In another embodment, the radiopaque marker projects outward from the stent.

In one embodiment, the security ring is in the form of a stretchable polymeric material. In a related embodiment, the security ring is in the form of a band of polymeric material having axially extending cutouts therein forming weakened regions staggered with respect to each other so that upon expansion of the security ring the weakened regions can break so that the polymeric band has a wave-like shape. In another embodiment the graft is a porous polymer. The porous polymer can be porous polyurethane or porous ePTFE.

In a second aspect, the invention includes a skeletal structure having a plurality of separate expandable metallic rings, an outer sleeve forming a graft, an inner polymeric sleeve disposed axially within the skeletal structure, and bands of a flexible material compatible with the polymeric material utilized for the inner and outer sleeves disposed between the expandable metallic rings and within and between the inner sleeve and the graft.

In a general embodiment, each expandable metallic ring includes first and second substantially circular elements having convolutions therein defining the outer margins of the expandable metallic ring and a plurality of circumferentially spaced-apart struts extending between the substantially circular elements and being joined therewith to maintain a predetermined axial spacing between the substantially circular elements so that the length of the ring is maintained during expansion of the ring. The convolutions can be sinusoidal having maximums and minimums, the maximum of one element being disposed opposite the maximum of the other element with the spaced-apart struts extending between the maximums.

In another general embodiment the polymer material for the inner sleeve or graft or both is a porous polymer. The porous polymer can be porous polyurethane or ePTFE. In one general embodiment, the polymer material for the inner sleeve is a porous polymer selected from the group consisting of porous polyurethane and porous ePTFE, and the polymer material for the graft is not porous. In another general embodiment, the polymer material for the graft is a porous polymer selected from the group consisting of porous polyurethane and porous ePTFE, and the polymer material for the inner sleeve is not porous.

In one embodiment, the bands are formed of FEP. In a related embodiment, the bands are bonded to the outer surface of the inner sleeve and to the inner surface of the outer sleeve.

In yet another general embodiment, at least one of the expandable metallic rings at one of the ends of the stent graft is formed of a radiopaque material with the other expandable metallic rings being formed of a less radiopaque material.

In still yet another general embodiment, the expandable metallic rings on opposite ends of the stent graft are formed of a radiopaque material.

The invention also includes a biologically active coating carried by the inner surface of the inner sleeve or the outer surface of the outer sleeve or both. In one embodiment the coating is P15. Means carried by the stent graft are included for providing local delivery of drugs or agents into the vessel after the stent graft has been positioned in the vessel. In one embodiment, the drug or agent is disposed in pockets formed in the rings and between the inner sleeve and the graft. In a related embodiment the drug or agent is in solid tablet form. In other embodiments, the drug or agent is in liquid form. The drug or agent can be in powder form. The drug or agent can be carried by a coating provided on the rings.

In yet another general embodiment, a stent graft assembly includes the stent graft described above, and a balloon delivery catheter having a distal extremity and having an inflatable balloon on the distal extremity, where said stent graft is disposed over the inflatable balloon.

In a further aspect, the invention concerns a method for manufacturing a stent graft for implantation in a vessel in a human body by the use of a sleeve of a flexible material compatible for use in a human body, expandable metallic rings and expandable bands formed of a flexible material and by the use of a mandrel having an outside diameter corresponding to the inside diameter of the inner sleeve. The method includes the steps of placing the inner sleeve over the mandrel, placing the rings and bands on the inner sleeve extending axially of the sleeve so that the rings and bands are substantially juxtaposed and are alternating with respect to each other axially of the sleeve and introducing an outer sleeve over the juxtaposed rings and bands and bonding the bands to the inner and outer sleeves. The outer sleeve can be formed by everting lengths of the inner sleeve extending from opposite ends to extend over the rings and bands to cover the rings and bands.

In one embodiment, the method also includes the step of coating the outer surface of the outer sleeve and the inner surface of the inner sleeve with a biologically active coating. In a related embodiment, the biologically active coating is the peptide P15 having the sequence (H-Gly-Thr-Pro-Gly-Pro-Gln-Gly-Ile-Ala-Gly-Gln-Arg-Gly-Val-Val-OH).

In another embodiment, the method also includes the step of sealing the ends of the inner and outer sleeves so that the rings and bands are encapsulated therein.

In yet another embodiment, the method also includes the step of coating the inner surface of the inner sleeve prior to its placement on the mandrel.

In a particular aspect, the invention concerns a method for assembling a stent graft onto a balloon delivery catheter. The method includes the steps of placing the stent graft on the delivery balloon of the delivery catheter, crimping the stent graft onto the balloon, positioning security rings on the opposite ends of the stent graft and crimping the security rings onto the stent graft to ensure that the graft will not become displaced with respect to the stent during deployment of the stent graft into the vessel of the patient.

In a further aspect, the invention includes a stent graft for implantation in a vessel in a human body comprising inner and outer coaxial tubular sleeves formed of a flexible material compatible for use in the human body and each having first and second ends, a plurality of separate expandable metallic rings disposed axially within and between the inner and outer sleeves and bands of a flexible material compatible with the flexible material utilized for the inner and outer sleeves disposed between the rings and within and between the inner and outer sleeves.

In another aspect, the invention includes a stent having first and second end regions, and including a plurality of first and second end regions, a plurality of struts connecting adjacent internal sinusoidal elements at full-wave intervals, and a plurality of struts connecting end-region sinusoidal elements to adjacent internal sinusoidal elements at half-wave intervals, to increase the density of the struts at said end regions.

In a final aspect, the invention includes an S-shaped link, for interconnecting sinusoidal elements in a stent and permitting axial bending between the elements. The link includes at least two regions of variable thickness to provide resistance to fatigue.

These and other objects and features of the invention will be more fully appreciated when the following detailed description of the invention is read in conjunction with the accompanying drawings.

Brief Description of the Drawings

Figure 1 is a side elevational view of a stent graft assembly incorporating the present invention mounted on the distal extremity of a balloon delivery catheter.

Figure 2 is a side elevational view of another embodiment of a stent graft assembly incorporating the present invention also mounted on the distal extremity of a balloon

delivery catheter.

Figure 3 is a cross-sectional view taken along the line 3-3 of Figure 2.

Figure 4 is a view similar to Figure 3 showing an alternate embodiment.

Figure 5 is a side elevational view of a stent graft assembly with a certain portion of the stent graft being removed and showing the use of different types of security rings.

Figure 6 is an enlarged view of one of the security rings shown in Figure 5.

Figure 7 is a partial isometric view of a stent graft incorporating the present invention

Figure 8 is an enlarged side elevational view of the stent graft shown in Figure 7 with certain portions being broken away.

Figure 9 is a side elevational view of the stent graft showing its method of manufacture.

Figure 10 is a partial cross-sectional view showing another embodiment of the stent graft of the present invention.

Figure 11 is a partial side elevational view of a stent graft incorporating the present invention with certain portions broken away which includes the capabilities for delivering drugs and/or agents.

Figure 12 is an enlarged cross-sectional view taken along the line 6-6 of Figure 11.

Figure 13 is a partial cross-sectional view of another embodiment of a stent graft incorporating the present invention having drug or agent delivery capabilities.

Figure 14 is a plan view of one embodiment of the invention which has been split apart longitudinally and spread out to show its construction.

Figure 15 is a view of a portion of the embodiment of Figure 14.

Figure 16 is an enlarged view of a S-shaped link having variable thickness.

Detailed Description of the Invention

The present invention generally concerns a stent graft for implantation in a vessel in a patient. The invention includes two aspects which are both illustrated in non-limiting embodiments below. The first aspect is described in Section A with respect to figures 1-6 and provides a stent graft formed of an expandable metal skeletal structure and having a graft in the form of a polymeric sleeve extending over the stent, and an expandable security ring securing each end of the graft to a corresponding end region of the stent. The second aspect is detailed in Section B with respect to figures 7-13 and provides inner and outer sleeves enclosing a plurality of separate expandable metallic rings and flexible bands. It

will also be appreciated from the discussion that the invention includes a combination of these two aspects. Additional features of the invention include end strut patterns optimized for graft support and variable thickness links for improved fatigue resistance.

A. In one aspect, the stent graft of the present invention comprises a stent formed of an expandable metal skeletal structure, and having first and second end regions, a graft in the form of a polymeric sleeve extending over at least a portion of the stent, the graft having first and second ends, and an expandable security ring securing each end of the graft to a corresponding end region of the stent. In one embodiment, a stent graft assembly for use in placing the stent graft in a vessel of a patient comprises a balloon delivery catheter having a distal extremity and having an inflatable balloon on the distal extremity. The stent graft is disposed over the inflatable balloon. First and second expandable security rings are disposed over the first and second ends of the graft and serve to secure the first and second ends of the graft to the stent to prevent inadvertent displacement of the sleeve with respect to the stent during deployment of the stent graft into the vessel of the patient.

More particularly as shown in Figure 1 of the drawings, the stent graft assembly 10 includes a stent graft 11 which consists of a stent 12 which is covered by a polymeric sleeve 13. As shown in Figure 1, the stent graft 11 is disposed over an inflatable balloon 16 on the distal extremity of a balloon delivery catheter 17 of a conventional type and forming a part of the assembly 10. The balloon delivery catheter 17 includes a multi-lumen shaft 18 which incorporates a balloon inflation lumen (not shown) and may incorporate a guide wire lumen (not shown).

The balloon delivery catheter 17 and the stent graft 11 consisting of stent 12 and the polymeric sleeve 13 are disclosed in co-pending application Serial No. 09/385,691 filed on August 30, 1999, and therefore will not be described in detail. As disclosed therein, the stent 12 is in the form of an expandable frame and consists of a plurality of axially spaced-apart circular belts 21 which are interconnected by sinusoidal interconnector 22. Each belt 21 is comprised of a plurality of circumferentially spaced-apart elongate struts 24. Sinusoidal -shaped elements 26 and 27 adjoin the ends of the struts 24 and form in conjunction therewith the circular belts 21. The sinusoidal-shaped interconnectors 22 provided for interconnecting the belts 21 are at circumferentially spaced-apart positions to provide a stent 12 which when expanded is capable of providing circumferential support while at the same time being axially flexible.

The stent 12 is typically formed of a suitable metal such as stainless steel, titanium and other metals and alloys thereof. It is desirable that the material utilized for the frame be biocompatible with the fluids and tissues of the human body.

The sleeve 13 is in the form of a tubular member of a size so that it can slip over the stent 12 when it is in an unexpanded condition and preferably has a length so that the extreme ends of the stent 12 extend beyond the sleeve as shown in Figure 1. The sleeve 13 is typically formed of a polymeric material such as ePTFE.

In order to ensure that the polymeric sleeve 13 remains in the desired position on the stent 12, security rings 36 and 37 have been positioned over the outer ends of the sleeve 13. The security rings 36 and 37 typically can be formed of a metal and preferably the same metal which is used for the stent 12 as for example stainless steel or titanium or alloys thereof. The rings 36 and 37 have sinusoidal-shaped convolutions 38 so that they can be expanded with the stent graft when the stent graft is expanded as hereinafter described. By way of example, the security rings can be formed from laser cut tubing in the same manner as stents having a suitable wall thickness of 0.003" to 0.006". The inner surfaces of the security rings can be left unpolished so that they have a rougher inner surface finish to enhance gripping to the outer surface of the sleeve 13. Alternatively, a texture can be applied to the inner surface to enhance the gripping capabilities of the security ring.

A radiopaque marker 41 is carried by at least one and if desired both of the security rings 36 and 37. Thus as shown, a radiopaque marker 41 is provided on the security ring 37 and can be of a suitable radiopaque material such as gold which has been cold worked or forged into an eyelet receptacle 42 formed as a part of the convolutions 38.

In use of the stent graft assembly 10 and the stent graft 11 of the present invention with the method of the present invention, the stent 12 can be placed upon a support mandrel (not shown) after which the sleeve 13 is slipped onto the stent to provide the stent graft 11. The stent graft 11 is then placed on the balloon 16 of the balloon delivery catheter 17. The stent graft 11 is then crimped onto the balloon 16 with a crimping tool (not shown). The security rings 36 and 37 are then placed over the sleeve 13 and crimped onto the ends of the sleeve 13 by a crimping tool to ensure that the security rings 36 and 37 remain in place on the ends of the sleeve 13 and also to ensure that the ends of the graft 11 frictionally engage the stent 12 to retain the sleeve 13 in the desired position on the stent 12. Alternatively, the security rings 36 and 37 and the stent graft 11 can be crimped simultaneously.

The stent graft assembly 10 shown in Figure 1 can now be utilized for positioning the stent graft 11 in a vessel of a patient in a conventional manner as for example by introducing the same through a femoral artery. The advancement of the stent graft 11 can be ascertained by observing the positioning of the radiopaque marker 41 and also by any radiopaque markers on the stent 12 and the balloon catheter 17. During advancement of the stent graft to the desired site, the security rings 36 and 37 serve to ensure that the sleeve 13 will not accidentally become dislodged or shifted in position on the stent 12. After the stent graft has been delivered to the desired position in the vessel of the patient, the balloon 16 of the balloon delivery catheter 17 can be expanded to expand the stent 12 and the sleeve 13 carried thereby as well as the security rings 36 and 37.

After the stent graft 11 has been delivered and then expanded the desired amount, the balloon 16 of the balloon delivery catheter 17 can be deflated and the balloon delivery catheter 17 removed in a conventional manner. The stent graft 11 will remain in place. Its position can be ascertained by observing the position of the radiopaque marker 41.

Another embodiment of a stent graft assembly incorporating the present invention is shown in the stent graft assembly 61 in Figure 2. The balloon delivery catheter 62 shown therein shows the use of radiopaque marker bands 63 and 64 positioned on a shaft 66 on opposite ends of the balloon 67 and held in place by suitable means such as an epoxy 68 and disposed on opposite ends of the stent graft 11 and serve as enlargements to prevent the inadvertent dislodgement of the stent and/or the graft from the balloon during deployment of the stent graft 11.

In addition as in the previous embodiments, security rings 71 and 72 are provided on opposite ends of the stent 12 and the sleeve 13. Security rings 71 and 72 are each comprised of two elongate elements 76 and 77 in the forms of waves or convolutions which are sinusoidal in shape and which are joined together by circumferentially spaced-apart axially extending struts 78 and eyelets 79. As with the security rings 36 and 37, it can be seen that the security rings 71 and 72 can be readily crimped into place and expanded in the same manner as the security rings 36 and 37. The eyelets 79 carry radiopaque markers 81. As with the security rings 36 and 37 the inner surfaces of the elements 76 and 77 can be left unpolished or with a textured surface for frictionally engaging the outer surface of the polymeric sleeve 13.

In order to further enhance the engagement between the polymeric sleeve 13 on the stent 12, the radiopaque marker 81 as shown in Figure 3 can protrude out of the eyelet 79 so that it can form an indentation 82 with the sleeve 13 which extends into an open space in

the stent 12 to further ensure a good engagement between the sleeve 13 and the stent 12 to prevent dislodgement of the sleeve 13 and ring 71 or 72 from the stent 12. In a similar manner as shown in Figure 4, an eyelet 86 provided on the stent 12 may also carry a radiopaque marker 87 protruding radially and forming an indentation 88 in the inner surface of the sleeve 13 and to extend into a space in the security ring 72 to further ensure good enqaqement between the sleeve 13 and the stent 12.

Operation and use of the stent graft assembly 61 shown in Figure 2 is very similar to that hereinbefore described with respect to Figure 1 with the principal difference being that the security rings 71 and 72 have enhanced friction engaging capabilities over the security rings 36 and 37 shown in Figure 1. In addition, the balloon delivery catheter 62 by providing the marker bands 63 and 64 on opposite extremities of the stent graft 11 also ensure that the stent graft 11 cannot accidentally become dislodged during deployment of the stent graft 11.

Still another embodiment of a stent graft assembly incorporating the present invention is shown in Figure 5 in which the balloon delivery catheter 62 as shown therein is similar to the one hereinbefore described. The stent graft 11 is also similar to those hereinbefore described. However, in Figure 5 there is shown the use of security rings 91,or 92 (showing two different designs) mounted on opposite ends of the sleeve 13. The security ring 91 is in the form of a stretchable polymer which can be stretched and fitted over one end of the sleeve 13 to frictionally retain the security ring 91 on the sleeve 13 and similarly to retain the sleeve 13 on the stent 12. Alternatively as shown with the security ring 92, a less stretchable band of polymeric material can be utilized which is provided with circumferentially spaced-apart cutouts 93 therein which as shown in detail in Figure 6 are positioned in such a manner so as to provide weakened regions 94 associated with each of the cutouts 93 but being staggered or provided on opposite sides of the security ring 92 so that when the stent graft 11 is expanded, these weakened regions will or can break apart to provide a zig-zag shape or a substantially sinusoidal wave-like shape for the expanded security ring 92. Thus it can be seen that a polymeric security ring can be provided which firmly secures the graft to the stent while still permitting expansion of the stent and graft after the stent graft assembly 11 has been deployed to the desired position.

From the foregoing it can be seen that there has been provided a stent graft assembly and method which makes it possible to ensure that the graft is maintained in the desired position on the stent at all times and particularly during deployment of the stent graft while readily accommodating expansion of the stent graft after the stent graft has

been deployed into the desired position. It also can be seen that use of the security rings serves to prevent inadvertent movement of the graft with respect to the stent or separation of the graft from the stent.

B. In the second aspect, the stent graft of the present invention comprises inner and outer coaxial tubular sleeves formed of a flexible material compatible for use in the human body and each having first and second ends. A plurality of separate expandable metallic rings are axially disposed along the length of the inner and outer sleeves between the inner and outer sleeves. Each ring is comprised of first and second substantially circular elements having convolutions therein defining outer margins of the ring and a plurality of circumferentially spaced-apart struts extending between said substantially circular elements and being joined therewith to maintain a predetermined axial spacing between the substantially circular elements whereby on expansion of the rings, the length of the rings and the length of the stent graft are maintained. Bands of a flexible material compatible with the material of the inner and outer sleeves are disposed between the rings and within and between the inner and outer sleeves.

More in particular, the stent graft 111 of the present invention as shown in Figures 9 and 10 has a multilayer construction which is comprised essentially of three layers in which an inner sleeve 112 serves as one layer and an outer sleeve 113 serves as another layer and a plurality of juxtaposed rings 116 and bands 117 form an intermediate or third layer. The inner and outer sleeves 112 and 113 are preferably formed of the same material. However, if desired they can be formed of different materials. The material used for the sleeves 112 and 113 should be flexible and stretchable, i.e. capable of expanding. The material should be suitable for implantation in a vessel in a human body and typically may be a polymer. The material should be compatible with tissue and blood of the human body. One polymer found to be particularly satisfactory is expanded PTFE commonly called ePTFE. The ePTFE is desirable because it is a material which has pores that can enhance cell growth when implanted in a vessel in the human body. In addition, the ePTFE is very soft and can be readily expanded from a delivery unexpanded mode to an expanded mode as hereinafter described.

It is desirable that the wall thickness of the material utilized for the inner and outer sleeves be quite thin as for example ranging from 0.001" to 0.008" and preferably from 0.002" to 0.003". In connection with the selection of wall thickness it should be appreciated that during expansion of the stent graft 111 as hereinafter described, the wall

thickness will decrease. The pore sizes can range .from 10 pm to 90 pm and preferably between 20 to 60 pm. Pore size can be selected to optimize desired biological responses.

The rings 116 are formed of a suitable material such as stainless steel, titanium or tantalum with the latter material being particularly useful where optimum radiopacity is desired. The rings 116 are typically formed from a tubular material which is laser cut to provide the desired geometry as for example the geometry which is shown in Figures 7 and 8 of the drawings. Thus each ring 116 consists of first and second substantially circular elements 121 and 122 which have convolutions 123 therein generally in the form of a sine wave in which the maximums of each sine wave of the elements 121 and 122 are disposed opposite each other and are joined together and maintained in a predetermined spaced-apart relationship by struts 126 which typically are elongate and straight. As hereinafter explained, the struts 126 serve to maintain the length of the rings 116 in a axial direction as the rings are expanded. The wall thickness of the material utilized for forming the rings 116 can have a thickness ranging from 0.002" to 0.004" which after laser cutting are polished internally and externally with the axial lengths of the rings ranging from 2-3mm. In order to reduce spacing between the circular elements 121 and 122 after expansion of the elements 121 and 122, a minimum of one element can be positioned so that it is opposite the maximum of another element.

The bands 117 are preferably formed of FEP (fluorinated ethylene polypropylene) because this material is very compatible with the ePTFE material utilized for the inner and outer sleeves 112 and 113. It is a particularly desirable material because it bonds very well to ePTFE when subjected to heat. Alternatively the bands 117 can be formed of PTFE which can be bonded to the sleeves by suitable means such as an adhesive or ultrasonic welding. It is desirable that the bands 117 be formed of a material which can fuse to the inner and outer sleeves 112 and 113.

The bands 117 typically preferably have the same wall thickness as the thickness of the material utilized for the rings 116. These bands 117 can have an axial length of 0.010" 0.050" with a preferable length ranging from 0.010" to 0.020". The bands 117 can have a wall thickness ranging from 0.001" to 0.004" to correspond to the thickness of the rings 116.

As can be seen from Figures 7 and 8, the rings 116 and the bands 117 are juxtaposed with respect to each other in alternating positions extending axially between the inner and outer sleeves 112 and 113. The inner and outer sleeves 112 and 113 can be bonded together by the use of the flexible bands 117 by applying heat to the outer sleeve

113 at appropriate circumferential locations. Alternatively, the entire multi-layer assembly can be placed in an oven at a suitable temperature ranging from 400 to 450°F for a suitable period of time as for example 3 to 5 minutes to cause bonding of the bands 117 to the inner surface of the outer sleeve 113 and the outer surface of the inner sleeve 112.

By way of example, manufacture of the stent graft of the present invention can be accomplished by the method which is shown in Figure 9 in which a cylindrical mandrel 151 is provided carried by supports 152 at opposite ends thereof. The mandrel 151 is formed of a suitable material such as stainless steel and is sized so that its outside diameter corresponds generally to the desired inside diameter of the inner sleeve 112.

In connection with the manufacture of the stent graft 111, it may be desirable prior to assembly to coat the surfaces of the inner sleeve 112 and the outer sleeve 113 which are to be in contact with blood and tissue of the human body with an appropriate bioactive/biocompatible coating such as that described in co-pending application Serial No. 09/385,692 filed August 30, 1999. In the manufacture of the stent graft of the present invention as shown in Figure 9, the tubing which is to be utilized for the inner sleeve 112 can be everted so that the inner surface is facing outwardly and coated after which the tubing can be returned to its initial state by reversing the folding of the sleeve material of the tubing. This tubing material can then be utilized for the inner sleeve 112 having an inner surface which is coated. By selecting an inner sleeve 112 which extends beyond the end of the stent approximately onehalf the length of the stent graft from opposite ends of the stent graft, a stent graft 111 can be provided which has coated inner and outer surfaces.

As shown in Figure 9, a sleeve 112 which has its inside surface coated as hereinbefore described is placed over the mandrel 151 so that the ends of the sleeve extend beyond the mandrel 151 as shown in Figure 9. As soon as this has been accomplished, the rings 116 and bands 117 can be placed sequentially over the inner sleeve 112 in appropriate positions on the sleeve so that the intermediate portion of the sleeve is covered by the rings 116 and bands 117 and with equal lengths of the sleeve extending beyond the intermediate portion. Thereafter, one end of the sleeve 112 as for example the right hand end as shown Figure 9 can be everted and folded over one-half of the juktaposed rings 116 and bands 117 to form a rounded end as shown on the left hand side of Figure 8 to thereby encapsulate the rings 116 and bands 117 and to thereby provide an inner sleeve 112 and an outer sleeve 113. In a similar manner the left hand side can be everted and folded over to enclose the remaining rings 116 and bands 117 to form another closed end to provide the inner sleeve 112 and the outer sleeve 113 and to form a seam 131 between the two half

portions of the inner sleeve 112 forming the outer sleeve 113. Thus the two ends of the half portions of the outer sleeve 113 can be bonded together by suitable means such as by the use of heat. As soon as this has been accomplished, the completed stent graft can be removed from the mandrel 151 and another stent graft fabricated in a similar manner.

Alternatively if desired, the inner sleeve 112 and the outer sleeve 113 can be formed of separate parts with the inner surface of the inner sleeve 112 being coated and with the outer surface of the outer sleeve 113 being coated. With the use of such separate inner and outer sleeves 112 and 113, the inner sleeve 112 can be inserted onto the mandrel 151 and thereafter the rings 116 and bands 117 can be sequentially positioned thereon throughout the length of the inner sleeve. Thereafter the outer sleeve 113 can be slid over the rings 116 and bands 117 to cover the same. After this has been accomplished, the inner and outer sleeves 112 and 113 can be cut into appropriate lengths by cutting adjacent a band 117 so that the inner space between the sleeves 112 and 113 will be sealed as shown in Figure 10.

In either of the methods utilized for manufacture of the stent graft shown in Figures 9 and 10 it may be desirable to provide radiopaque markers at opposite ends of the stent graft to facilitate its placement in a vessel as hereinafter described. This can be readily accomplished by selecting rings 116 at opposite ends of the stent graft which are formed of a more radiopaque material as for example titanium or tantalum whereas intermediate rings can be formed of a less expensive material such a stainless steel.

In connection with the stent graft of the present invention, it has been found that it may be desirable to utilize the stent graft to locally deliver different drugs or agents into the vessel into which the stent graft is to be implanted to improve the vascular benefit and long term performance of the stent graft. Types of drugs or agents that may prove beneficial include substances that reduce the thrombogenic, inflammatory or smooth muscle cell proliferative response of the vessel to the stent graft. Specific examples of such drugs or agents may include heparin, phosphorylcholine, albumin, dexamethasone, paelitaxel and vascular endothelial growth factor (VEGF).

The drug or agents can be incorporated into the stent graf t in various ways. For example the drug or agent can be injected in the form of a gel or powder into spaces or pockets provided by the rings 116 between the elements 121, 122 and the struts 126 which are encapsulated between the inner and outer sleeves 112 and 113. Alternatively the stent graft 111 can be coated with a drug loaded polymer matrix which dissolves in the body fluids after implantation into the vessel. Alternatively, the drug or agent can be supplied in

a powder which has been formed into a solid tablet 161 positioned between the convolutions 123 as shown in Figures 11 and 12. Such tablets would gradually dissolve after implantation because of the porous nature of the inner and outer sleeves 112 and 113 formed of ePTFE.

Another embodiment of the stent graft incorporating the present invention is shown in Figure 13 in which the drug is delivered by a drug loaded coating 166 provided on the stent 116. Such a coating would release its drug carried thereby upon implantation of the stent graft in the vessel of the patient. In addition as shown in Figure 13, a dissolvable polymer 171 can be provided in the interstices between the convolutions 123 of the rings 116. As an alternative, the stent graft can be soaked in a solvent with a drug after assembly with the solvent being flashed off to leave the drug disposed in the interstices of the material utilized for forming the inner and outer sleeves 112 and 113.

The drugs delivered in the manner described above can introduce the drugs or agents in a delivery matrix which dissolves in a liquid environment. Alternatively the drug or agent can be delivered in a delivery matrix which liquefies at an elevated ("body") temperature. Also it should be appreciated that a dilatation balloon which typically is used for delivering a stent graft of the type hereinbefore described can be utilized for forcing a drug or agent out of pockets formed between the inner and outer sleeves during delivery of the stent graft into the vessel.

After the stent graft has been manufactured in the manner hereinbefore described it can be crimped onto the balloon of a balloon delivery catheter and delivered into a vessel in a conventional manner as for example through the femoral artery of a patient to a vessel within the body of the patient as for example an arterial vessel in the wall of the heart. The movement of the stent graft 111 can be readily observed by observing the radiopaque rings carried by the extremities of the stent graft. When it is properly positioned, the balloon can be inflated to expand the stent graft 111 into the desired location. The rings 116 and the bands 117 in the inner and outer sleeves 112 and 113 readily accommodate the desired expansion to a suitable size as for example from 2-5 mils. This expansion of the stent graft can be accommodated without changing the length of the stent graft because the struts 126 maintain the axial lengths of the rings and thereby maintain the axial length of the stent graft 111. The rings 116 provide the desired circumferential rigidity and serve to maintain the stent graft in the expanded position. Since there is no metal interconnecting the rings 116, the flexible bands 117 disposed between the rings serve to provide flexibility in the stent graft so that the stent graft can readily accommodate any bends in the vessel during

and after deployment. For this reason, the stent graft can be readily positioned in the desired location.

When the stent graft which has been positioned in the vessel has been manufactured and assembled to incorporate drug or agent delivery capabilities as hereinbefore described, the drug or agent which has been incorporated therein is locally delivered from the stent graft to provide the desired results as for example to provide vascular benefits and enhance the long term performance of the stent graft.

The stent graft and method of the present invention have many advantages. There has been provided a stent graft which is physiologically compatible and highly flexible and is comprised of a minimum number of materials and elements which are exposed to blood and tissue in the human body. Because of the construction, the metal which is used for the rings is completely encapsulated within the inner and outer sleeves. Thus only one material as for example the ePTFE which is utilized for the inner and outer sleeves is introduced into the vessel. In utilizing coatings for the stent graft for various purposes as for example inhibiting clotting, enhancing endothelial growth, etc., these can be accomplished by a single coating process because only one material need be coated. In contrast to a situation where both metal and a polymer are exposed to the blood and tissue, both must be coated in separate processes. The desired radiopacity at the extremities of the stent graft can be readily achieved because since the rings are modular components of the stent graft, only one or possibly two need be made of the more expensive radiopaque material. By the elimination of connecting metal between the metallic rings, the flexibility of the stent graft is greatly increased. The flexible bands provided between the rings provide circumferential support between the rings. They also serve as circumferential lines of attachment between the inner and outer sleeves and also provide for support of the spaces between the rings. The construction utilized for the stent graft is one which lends itself to ease of manufacture and less labor intensive manufacture. The construction utilized also lends itself for delivery of drugs or agents to improve the vascular benefit and long term performance of the stent graft.

Another embodiment of the stent graft of the present invention includes an end strut pattern optimized for graft support. Figure 14 is a plan view of one embodiment of a stent 207 illustrating sinusoidal-shaped end elements 200 and 201 which are provided on opposite ends of the plurality of serially connected belts 202. Belts 202 are axially aligned with each other. The end belts 225 and 226 are provided with interconnecting means 205 for connecting the internal sinusoidal-shaped elements 210 and 211 and the end, external

sinusoidal portions 200 and 201, respectively so that the ends of the graft are optimized to support the graft as described below.

The means 205 consists of at least one strut which is relatively short in length in comparison to the length of the elongate struts 215. As illustrated in Figure 14, twice as many struts 205 as elongate struts 215 are provided per belt to prevent the ends of the graft from falling though the end belts 225 and 226 of the stent 207. In other words, struts 205 connect the external sinusoidal elements 200 and 201, to adjacent internal sinusoidal elements 210 and 211, respectively, at half-wave intervals. This functions to increase the density of the struts 205 at the end regions. Elongate struts 215 connect adjacent internal sinusoidal elements at full-wave intervals.

Also provided are interconnecting means 220 for connecting the plurality of belts 202 and the sinusoidal-shaped portions 210 and 211 so that the belts 202 and end belts 225 and 226 extend along an axis while permitting axial bending between the belts 202 and the end portions 225 and 226, and while maintaining a constant length of the stent 207. The means 220 consists of at least one ring 230 and a plurality of S-shaped links 232. The rings 230 can be adapted to secure radiopaque markers on the stent to fluoroscopically position the stent by observing the locations of the markers. Thus, as shown in Figure 14, between each sinusoidal-shaped portion 210 and 211 and belt 202 there is provided a single ring-shaped link 230 and two S-shaped links 232.

The S-shaped links 232 can be foldable and can be either uniform in thickness or of variable thickness as shown in Figure 16. A variable thickness S-shaped link 232 has thicker portions 250 and 251 relative to portion 255 for improving resistance to fatigue during axial bending between the belts 202, 225, and 226.

As illustrated in Figure 1, a polymeric sleeve 13 can also be positioned over the stent 207 shown in Figure 14. In order to ensure that the polymeric sleeve 13 remains in the desired position on the stent 12, security rings 36 and 37 can be positioned over the outer ends of the sleeve 13. The security rings 36 and 37 have sinusoidal-shaped convolutions 38 so that they can be expanded with the stent graft when the stent graft is expanded. Likewise, security rings 91, as shown in Figure 5 can also be positioned over the outer ends of the sleeve 13 in combination with the stent 207 shown in Figure 14. As described above, the security ring 91 can be in the form of a stretchable polymer which can be stretched and fitted over one end of the sleeve 13 to frictionally retain the security ring 91 on the sleeve 13 and similarly to retain the sleeve 13 on the stent 207 shown in Figure 14.

From the foregoing, it can be seen how various objects and features of the invention are met. Although the invention has been described with respect to particular embodiments, it will be apparent to those skilled in the art that various changes and modifications can be made without departing from the invention.

IT IS CLAIMED:

1. A stent graft for implantation in a vessel of a patient comprising

a stent formed of an expandable metal skeletal structure, and having first and second end regions;

a graft in the form of a polymeric sleeve extending over at least a portion of the stent, the graft having first and second ends; and

an expandable security ring securing each end of the graft to a corresponding end region of the stent.

2. The stent graft of claim 1, in which the security rings are formed of metal.

3. The stent graft of claim 1, in which the security rings have a roughened surface for engaging the outer surface of the graft to enhance frictional engagement between the security ring and the graft.

4. The stent graft of claim 1, wherein the security rings are formed of elongate metal elements having convolutions therein to permit expansion of the security ring.

5. The stent graft of claim 1, which further includes a radiopaque marker carried by the security ring.

6. The stent graft of claim 5, wherein one of said security rings includes an eyelet and wherein said radiopaque material is disposed in the eyelet.

7. The stent graft of claim 6, wherein said radiopaque marker projects in a direction so that it forms a depression in the graft to help ensure that the graft and ring will not become displaced with respect to the stent.

8. The stent graft of claim 1, which further includes a radiopaque marker carried by the stent.

9. The stent graft of claim 8, wherein the stent includes an eyelet and wherein said radiopaque material is disposed in the eyelet.

10. The stent graft of claim 9, wherein said radiopaque marker projects outward from the stent.

11. The stent graft of claim 1, wherein said security ring is in the form of a stretchable polymeric material.

12. The stent graft of claim 1, wherein said security ring is in the form of a band of polymeric material having axially extending cutouts therein forming weakened regions staggered with respect to each other so that upon expansion of the security ring the weakened regions can break so that the polymeric band has a wave-like shape.

13. The stent graft of claim 1, wherein said graft is a porous polymer selected from the group consisting of porous polyurethane and porous ePTFE.

14. The stent graft of claim 1, where said skeletal structure comprises a plurality of separate expandable metallic rings, and where said stent graft further comprises

an inner polymeric sleeve disposed axially within the skeletal structure; and

bands of a flexible material compatible with the polymeric material utilized for the inner and outer sleeves disposed between the expandable metallic rings and within and between the inner sleeve and the graft.

15. The stent graft of claim 14, wherein each expandable metallic ring is comprised of first and second substantially circular elements having convolutions therein defining the outer margins of the ring and a plurality of circumferentially spaced-apart struts extending between said substantially circular elements and being joined therewith to maintain a predetermined axial spacing between the substantially circular elements so that the length of the ring is maintained during expansion of the ring.

16. The stent graft of claim 15, wherein said convolutions are generally sinusoidal having maximums and minimums, the maximum of one element being disposed opposite the maximum of the other element with the spaced-apart struts extending between the maximums.

17. The stent graft of claim 14, wherein said polymer material for the inner sleeve or graft or both is a porous polymer selected from the group consisting of porous polyurethane and porous ePTFE.

18. The stent graft of claim 14, wherein said polymer material for the inner sleeve is a porous polymer selected from the group consisting of porous polyurethane and porous ePTFE; and where the polymer material for the graft is not porous.

19. The stent graft of claim 14, wherein said polymer material for the graft is a porous polymer selected from the group consisting of porous polyurethane and porous ePTFE; and where the polymer material for the inner sleeve is not porous.

20. The stent graft of claim 14, wherein said bands are formed of FEP.

21. The stent graft of claim 14, wherein the bands are bonded to the outer surface of the inner sleeve and to the inner surface of the outer sleeve.

22. The stent graft of claim 14, wherein at least one of the expandable metallic rings at one of the ends of the stent graft is formed of a radiopaque material with the other expandable metallic rings being formed of a less radiopaque material.

23. The stent graft of claim 14, wherein the expandable metallic rings on opposite ends of the stent graft are formed of a radiopaque material.

24. The stent graft of claim 14, which further includes a biologically active coating carried by the inner surface of the inner sleeve or the outer surface of the outer sleeve or both.

25. The stent graft of claim 14, which further includes means carried by the stent graft for providing local delivery of drugs or agents into the vessel after the stent graft has been positioned in the vessel.

26. The stent graft of claim 14, wherein the drug or agent is disposed in pockets formed in the rings and between the inner and outer sleeves.

27. The stent graft of claim 14, wherein the drug or agent is in a form selected from the group consisting of:

(a) solid tablet form;

(b) liquid form;

(c) powder form; and

(d) carried by a coating provided on the expandable metallic rings.

28. A stent graft assembly comprising,

the stent graft of claim 1, and

a balloon delivery catheter having a distal extremity and having an inflatable balloon on the distal extremity, where said stent graft is disposed over the inflatable balloon.

29. A method for manufacturing a stent graft for implantation in a vessel in a human body by the use of a sleeve of a flexible material compatible for use in a human body, expandable metallic rings and expandable bands formed of a flexible material and by the use of a mandrel having an outside diameter corresponding to the inside diameter of the inner sleeve comprising placing the inner sleeve over the mandrel, placing the rings and bands on the inner sleeve extending axially of the sleeve so that the rings and bands are substantially juxtaposed and are alternating with respect to each other axially of the sleeve and introducing an outer sleeve over the juxtaposed rings and bands and bonding the bands to the inner and outer sleeves.

30. A method as in Claim 29 wherein the outer sleeve is formed by everting lengths of the inner sleeve extending from opposite ends to extend over the rings and bands to cover the rings and bands.

31. A method as in Claim 29 further comprising the step of coating the outer surface of the outer sleeve and the inner surface of the inner sleeve with a biologically active coating.

32. A method as in Claim 29 further including the step of sealing the ends of the inner and outer sleeves so that the rings and bands are encapsulated therein.

33. A method as in Claim 29 further including the step of coating the inner surface of the inner sleeve prior to its placement on the mandrel.

34. A method for assembling a stent graft onto a balloon delivery catheter comprising placing the stent graft on the delivery balloon of the delivery catheter, crimping the stent graft onto the balloon, positioning security rings on the opposite ends of the stent graft and crimping the security rings onto the stent graft to ensure that the graft will not become displaced with respect to the stent during deployment of the stent graft into the vessel of the patient.

35. A stent having first and second end regions, and comprising

a plurality of first and second end regions;

a plurality of struts connecting adjacent internal sinusoidal elements at full-wave intervals; and

a plurality of struts connecting end-region sinusoidal elements to adjacent internal sinusoidal elements at half-wave intervals, to increase the density of the struts at said end regions.

36. An S-shaped link, for interconnecting sinusoidal elements in a stent and permitting axial bending between the elements, comprising

at least two regions of variable thickness to provide resistance to fatigue.

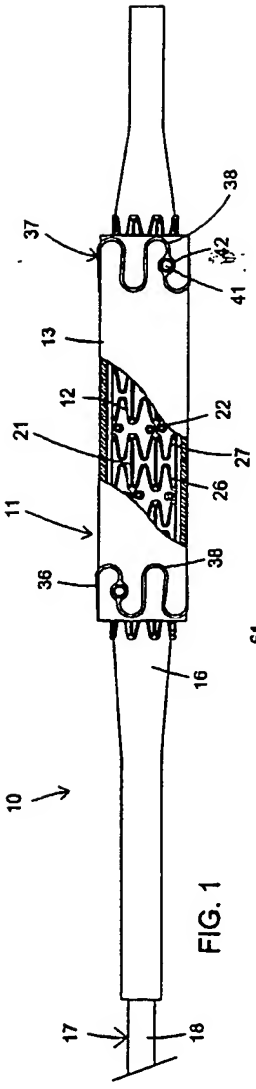

FIG. 1

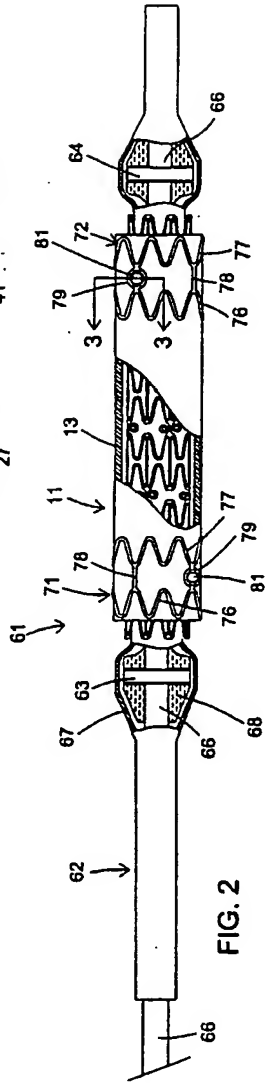

FIG. 2

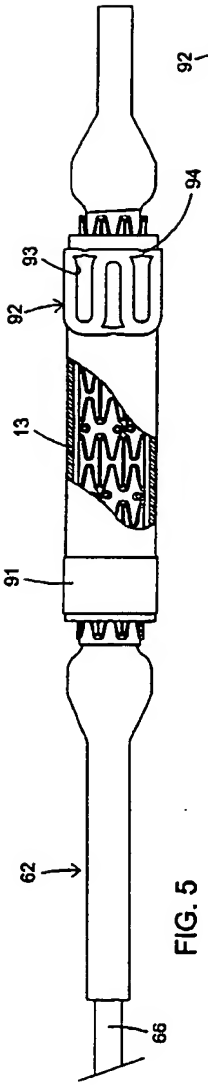

FIG. 5

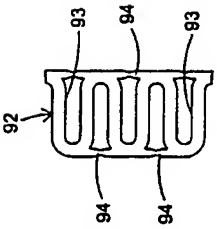

FIG. 6

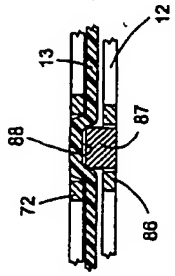

FIG. 4

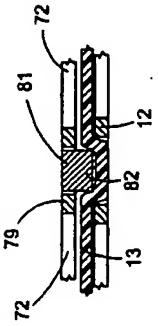

FIG. 3

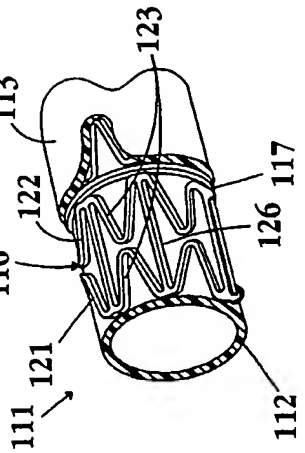

Fig. 7

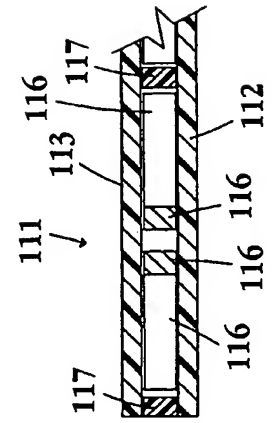

Fig. 10

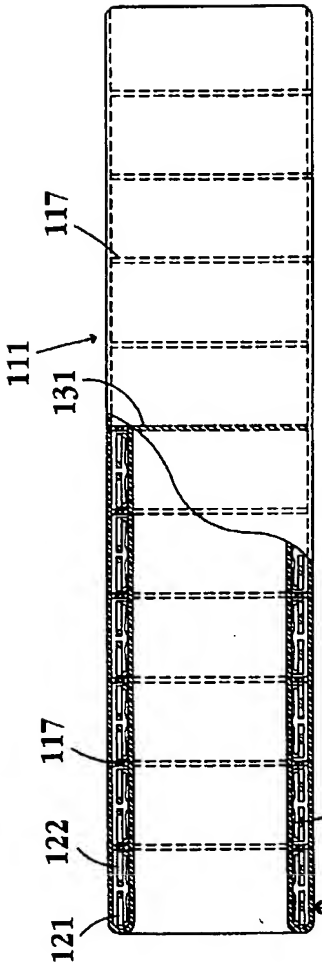

Fig. 8

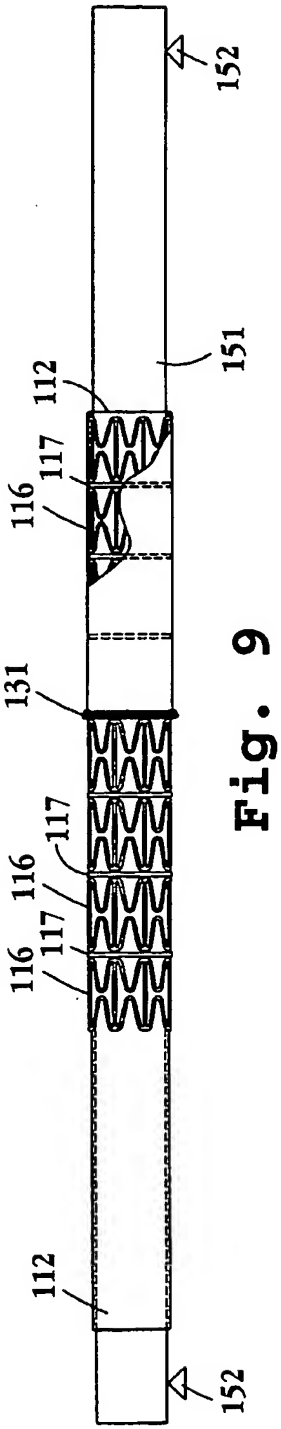

Fig. 9

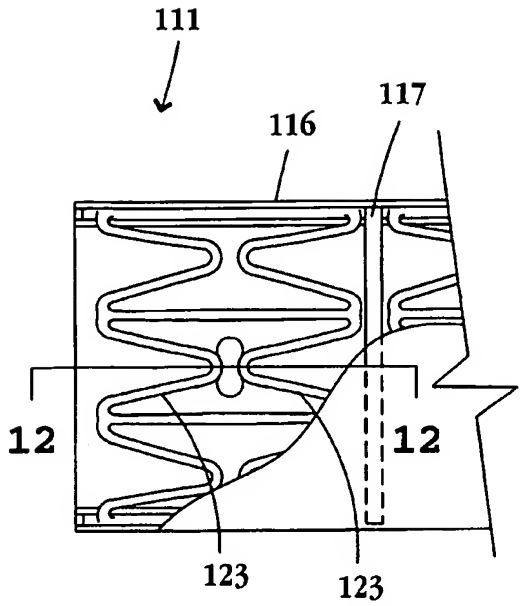

Fig. 11

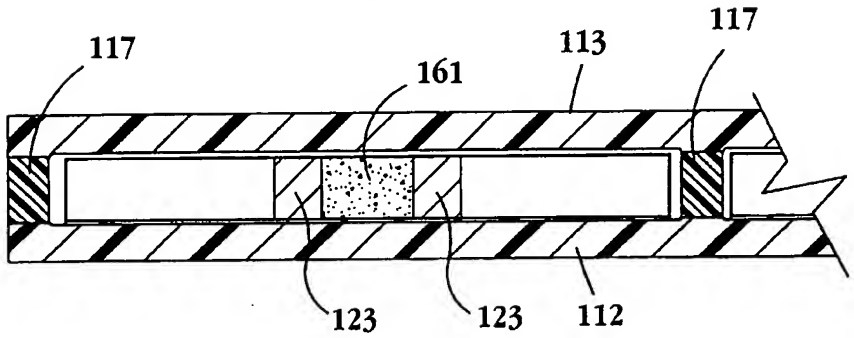

Fig. 12

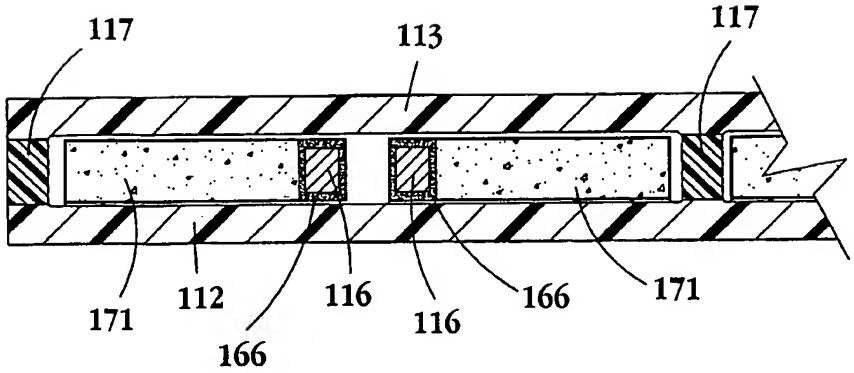

Fig. 13

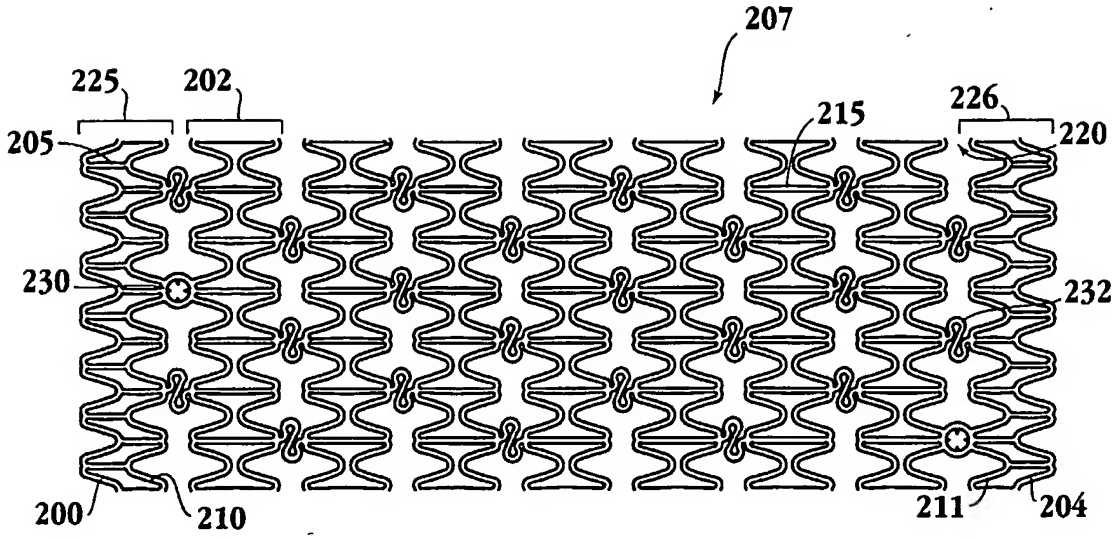

Fig. 14

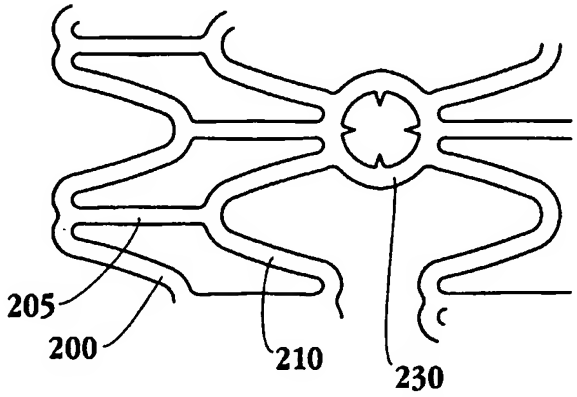

Fig. 15

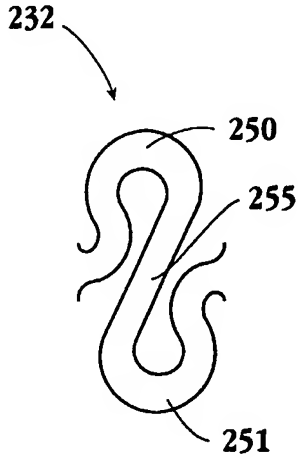

Fig. 16